2004 FDA WORKSHOP ON PRE-CLINICAL TESTING *FOR* ENDOVASCULAR GRAFTS

Conference Overview

We are pleased to announce the second FDA Workshop on Preclinical Testing for Endovascular Grafts.

Dates: July 28 – 29, 2004

Location: Hilton Washington, DC North in Gaithersburg, MD

FDA Steering Committee:
Dorothy B. Abel
Marianne Grunwaldt
Angela C. Smith

Scientific Advisory Committee:
Mark M. Dehdashtian
Stuart T. Rodger
Louis J. Smith
Matthew S. Waninger, PhD

As with the previous meeting, representatives from various areas involved with the development, testing and use of endovascular grafts have been invited. There will be four sessions during the workshop: 1) animal studies; 2) fixation effectiveness and sealing; 3) implant integrity; and 4) past, present and future issues in pre-clinical testing. Each session will begin with short presentations followed by discussion from the participants and audience.

Venue & Location

The 2004 FDA Workshop on Preclinical Testing for Endovascular Grafts will be held at the Hilton Washington, DC North, located at 620 Perry Parkway in Gaithersburg, MD. For more information and for reservations please call: 301-977-8900 or visit the Hilton Hotels web site at www.hilton.com.

Participation

Participation in the Workshop will consist of both invited participants and audience members. The invited participants include representatives from various areas involved with the development of endovascular grafts such as industry, the medical community and testing facilities. Invited participants completed a work assignment in advance of the meeting in order to optimize the time spent during the workshop. There will be a limit of two participants per organization at each of the four sessions with a total of eight participants per organization. Audience participation is open to all who are interested in the pre-clinical testing of endovascular grafts and will be scheduled throughout the sessions.

Attire

The attire for both days will be business casual.

Sponsors

The Workshop is sponsored by the Food and Drug Administration and the Center for Devices and Radiological Health.

Additional Information

www.fda.gov/cdrh/meetings/072804workshop/

WORKSHOP OBJECTIVES

Session 1:

Animal Studies: A Retrospective and Prospective Evaluation

1. Describe animal studies previously conducted.
2. Identify what has been learned from various animal models.
3. Describe what has not been adequately evaluated in animal studies.
4. Identify potential modifications to improve animal studies.
5. Describe what animal studies should look like in the future.

Session 2:

Sealing and Fixation Effectiveness

1. Identify preclinical testing conducted to evaluate sealing and fixation effectiveness.
2. Identify what has been learned from current testing (e.g., characterization, identification of poor designs).
3. Describe the limitations of current testing to predict clinical performance.
4. Identify potential modifications to current testing methodology.
5. Discuss special considerations for adjunctive devices (e.g., cuffs, extensions, stents).

Session 3:

Device Integrity, Fatigue and Durability

1. Identify preclinical testing conducted to evaluate device integrity, fatigue and durability.
2. Identify what has been learned from current testing (e.g., characterization, identification of poor designs).
3. Describe the limitations of current testing to predict clinical performance.
4. Identify potential modifications to current testing methodology.
5. Discuss special considerations for adjunctive devices (e.g., cuffs, extensions, stents).

Session 4:

Clinical and Preclinical Performance: Past, Present and Future

1. Describe clinical perspective and preclinical philosophy three years ago.
2. Describe current clinical perspective and preclinical philosophy.
3. Discuss future goals and objectives.

WORKSHOP AGENDA

Wednesday, July 28

9:00 am Opening Remarks

Welcome
Donna-Bea Tillman, PhD
ODE Director
Introduction
Dorothy B. Abel

Session 1 9:30 am-1:00 pm
Animal Studies: A Retrospective and Prospective Evaluation

9:30 Presentation
Clinical and Scientific Perspective
Michael J. Hallisey, MD

9:45	Participant Discussion
10:15	Audience Participation
10:30	Break
11:00	Continued Discussion
12:15	Audience Participation
12:45 pm	Session Wrap-up
1:00	Lunch

Session 2 2:00-6:00 pm
Sealing and Fixation Effectiveness

2:00 Presentations
Clinical Perspective
Mark F. Fillinger, MD
Scientific Perspective
Robert G. Whirley, PhD

2:15	Participant Discussion
3:15	Audience Participation
3:30	Break
4:00	Continued Discussion
5:15	Audience Participation
5:45	Session Wrap-up
6:00	Adjourn

Thursday, July 29

Session 3 9:00 am-1:00 pm
Device Integrity Fatigue and Durability

9:00 Presentations
Clinical Perspective
Timothy A.M. Chuter, MD
Scientific Perspective
Louis J. Smith

9:15	Participant Discussion
10:15	Audience Participation
10:30	Break
11:00	Continued Discussion
12:15	Audience Participation
12:45 pm	Session Wrap-up
1:00	Lunch

Session 4 2:00-6:00 pm
Clinical and Preclinical Performance: Past, Present and Future

2:00 Presentations
Clinical Perspective
Roy K. Greenberg, MD
Regulatory/Scientific Perspective
Dorothy B. Abel

2:15	Participant Discussion
3:15	Break
3:30	Audience Participation
4:00	Workshop Wrap-up
5:00	Adjourn